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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,371	03/16/2001	John EN Morton	P277176	9624
909	7590	07/22/2002	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			MYERS, CARLA J	
ART UNIT	PAPER NUMBER			
1634	10			
DATE MAILED: 07/22/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,371	MORTEN, JOHN EN	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 February 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 6 and 7 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6 and 7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

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1. This action is in response to Paper No. 8, filed February 27, 2002. Applicants arguments presented in the response of Paper No. 8 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This rejection is made FINAL.

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to methods for detecting a polymorphism in the human VCAM-1 gene. The claimed methods and nucleic acids are not supported by either a specific and substantial asserted utility or a well-established utility. The specification teaches that the polymorphisms are present in the promoter region of VCAM-1 and that the polymorphisms alter known transcription factor binding sequences (see, for example, pages 14-15). However, the specification does not teach that an alteration at any of the specified nucleotide positions alters expression of VCAM-1. The specification (pages 6-7) suggests that the disclosed polymorphisms can be used to diagnose disease, or can be used to develop drugs for the treatment of diseases or can be used to evaluate the efficacy of therapeutic compounds. However, the specification has not clearly taught an association between the disclosed VCAM-1

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polymorphisms and the occurrence of disease. Therefore, it is clear that further research would be required to practice the claimed methods and to use the disclosed polymorphisms because this would require identifying a disease which is correlated with the presence of the VCAM-1 polymorphisms. The use of the claimed method to search for diseases that are correlated with the VCAM-1 polymorphisms constitutes a research use only and does not constitute a “real world” context of use. As stated in *Brenner v. Manson*, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966) “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion”. Furthermore, the concept of analyzing a gene for a polymorphism to determine the status of an individual is considered to be a general use and is not considered to be a substantial, specific utility. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

Response to arguments:

In the response of Paper No. 8, Applicants traverse this rejection by stating that the claims have been amended to recite “an assay for detecting a nucleotide polymorphism”. It is asserted that there are many uses for such an assay, such as for characterizing an individual in terms of haplotype. Applicants arguments have been fully considered but are not persuasive. Characterizing an individual in terms of their haplotype is considered to be a general, non-specific utility. The specification has not disclosed an association between any of the VCAM-1

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polymorphisms or haplotypes containing the VCAM-1 polymorphisms and any particular conditions or diseases. The specification does not teach use of a haplotype containing one of the VCAM-1 polymorphisms in for a substantial and specific purpose. Accordingly, it is maintained that the claimed methods for detecting a nucleotide polymorphism in the VCAM-1 gene are not supported by a specific or substantial or well-established utility.

3. Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, or credible asserted utility or well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Response to arguments:

In the response of Paper No. 8, Applicants traverse this rejection for the same reasons stated in paragraph 3 above. Accordingly, the response to those arguments presented in paragraph 3 above apply equally to the present grounds of rejection.

4. Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6 and 7 are indefinite over the recitation of "EMBL ACCESSION NO: M92431" because it is not clear as to what is encompassed by this phrase. The sequences listed in an EMBL database are continuously updated and modified. Therefore, there is no single, constant definition for the sequence presented as EMBL Accession No. M92431. It is suggested

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that the claims be amended to refer to the position of the polymorphism relative to the start site, to the extent that this is supported by the specification or use a numbering scheme relative to a specific nucleotide sequence provided in a sequence listing.

Response to arguments:

In the response of Paper No. 8, Applicants traverse this rejection by stating that the response includes a copy of the printout of EMBL Accession No. M92431. It is stated that the Examiner has not "explained how or why this published sequence could be revised". Applicants state that the sequence cannot be revised unless "perhaps, a sequencing error were to be found". Applicants arguments have been fully considered but are not persuasive to overcome the present grounds of rejection. The fact that the EMBL sequence can be modified if an error occurs clearly indicates that an EMBL accession no. does not represent a single fixed sequence. Rather, the EMBL sequence is one which can be modified and updated in any manner, at any point in time. Therefore, there is no fixed definition for what constitutes "EMBL Accession No. M92431". As shown in the attached NCBI printout, as of July 18, 2002, the sequence of M92431 has been revised twice. The sequence was first filed on August 3, 1993, updated on October 3, 1994 and again updated January 18, 1995. When sequences are revised, the record does not necessarily indicate what modifications have been made to the sequence and records of the earlier filed sequence are often removed. Thus, when Applicants refer to the sequence of EMBL Accession No. M92431, it is unclear as to whether Applicants intend to refer to the sequence of the

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sequence of August 3, 1992, the sequence of October 3, 1994 or the sequence of January 18, 1995, or to any later modified sequence.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

July 18, 2002

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER